

CLARIFICATION OF STYRENE RANKING

There appears to be some confusion concerning the way the EPA is ranking styrene in the 112(g) proposed rulemaking and about the current data pertaining to the hazard of that chemical. The following information should help clarify how styrene is ranked under the proposed rulemaking for section 112(g) of the Clean Air Act Amendments of 1990 and the basis for its ranking. The data supporting the ranking of styrene and other hazardous air pollutants under section 112(g) are contained in a technical support document entitled "Technical background document to support rulemaking pursuant to the Clean Air Act-section 112(g): ranking of pollutants with respect to human health" and is available on the Technology Transfer Network.

Under section 112(g) of the Act, pollutants listed under section 112(b) as hazardous air pollutants (HAP) must be ranked by hazard to human health and classified as either having a safety threshold of exposure or not. The EPA's current guidance for assessing the risk of cancer causing substances, i.e., carcinogens is used to help identify "non-threshold" HAP in the ranking. Consequently, it is assumed that carcinogens have no safety threshold of exposure or that some hazard is presumed to exist with any level of exposure.

In the proposed section 112(g) rule, the EPA is making a risk-management/policy decision that any HAP with either an EPA or IARC (International Agency for Research on Cancer) weight-of-evidence classification for carcinogenicity indicating that the pollutant is either a known, probable, or possible human carcinogen will be treated as a "non-threshold" pollutant for the purposes of section 112(g). The EPA will be taking comment on the criteria used for identification of "non-threshold" HAP during the public comment period of the proposed section 112(g) rulemaking. The public is urged to provide comments on this and many more issues at that time.

The carcinogenic evidence for styrene has been evaluated by IARC in 1987 and was classified, according to their guidelines, to be in Group 2B (at least a possible human carcinogen). IARC based their overall conclusion on "limited" evidence in animals, "inadequate" evidence in humans, and positive mutagenicity (for styrene and its product of metabolism styrene oxide, classified in Group 2A as a probable human carcinogen).

A draft Drinking Water Criteria Document for styrene was presented to EPA's Science Advisory Board (SAB) in 1988 for

review. The SAB considered the evidence on styrene as classified into an EPA Group C (possible human carcinogen). They recommended that "there is insufficient evidence to justify the reclassification of styrene to EPA's category B2 and recommend continuation of the category C classification". The issue under discussion was the classification of styrene into Group C or Group B2. Whether there was sufficient evidence for styrene to at least be a possible human carcinogen was not an issue. Although IARC has assigned a weight-of-evidence indicating that styrene is a possible human carcinogen, no official EPA weight of evidence classification for styrene currently exists.

The Office of Drinking Water has more recently promulgated a final maximum contaminant level goal (MCLG) for Styrene (40 CFR parts 141,142 and 143 January 30, 1991). For the MCLG, styrene was treated like compounds who have EPA weight-of-evidence classifications of Group C, that is, styrene was placed into category II for the purposes of setting an MCLG (U.S. EPA, 1991).

The treatment of styrene, for the purposes of setting a MCLG under the water rule, provides a reasonable basis for the treatment of styrene under section 112(g) of the Clean Air Act Amendments of 1990. In the absence of an official EPA weight-of-evidence classification for styrene, styrene is treated like HAP having an EPA classification of Group C for the purposes of ranking hazard under section 112(g) and is assigned the category of "non-threshold" pollutant in the proposed rulemaking. Its classification as a possible carcinogen under IARC alone would satisfy the criteria for placement into this category. A similar situation exists for the basis of assignment of a de minimis level for this compound. The public is also asked to comment on the criteria used for assignment of de minimis levels for the section 112(g) rulemaking.

There is an epidemiological study, cited by the plastic industry involving styrene, which has just been accepted for publication and has not undergone Agency review at the current time. There are also studies underway involving animals which may provide further insight into the nature of the toxicity elicited by this compound. Additionally, the 90-day public comment period for the proposed rulemaking may provide an opportunity for any additional information concerning the toxicology of styrene to be submitted by the public. If the Agency assigns a weight-of-evidence classification to styrene before the promulgation of the section 112(g) rulemaking, that classification will be reflected in the final ranking. As in

the water rule, an official EPA weight-of-evidence classification is not being assigned to styrene in the section 112(g) rulemaking.

Recently an announcement appeared in the Canada Gazette on Feb. 5, 1994 which was a summary of Canada's health risk assessment for styrene under the Canadian Environmental Protection Act (CEPA). This statement only presented findings with respect to CEPA "toxic" (noncancer effects) and did not mention the Canadian classification of styrene as "possibly carcinogenic to humans". Some have used this announcement to make inferences concerning styrene's carcinogenicity characterization. This announcement was taken from a summary contained in a published report (Canadian Environmental Protection Act. Priority substance list assessment report . Styrene. Environment Canada/Health Canada. 1993) in which styrene is officially classified as a "possible human carcinogen". A more detailed assessment from the Canadian government is contained in the background document entitled : CEPA PSL Supporting Documentation: Health Related Section . Styrene. May 1993.